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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): **AYER et al.**

Serial No: **Not Yet Assigned**

Filed: **Herewith**

For: **UNIFORM DRUG DELIVERY
THERAPY**

Group Art Unit: **1615**

Examiner: **Siedleck, B.**

Preliminary Amendment

PRELIMINARY AMENDMENT

Honorable Commissioner of
Patents and Trademarks
Washington, D. C. 20231

Sir:

Please amend the above-identified patent application as follows:

AMENDMENTS

In the claims:

Please cancel claims 1-43.

Please add claims 44-58 as follows:

44. A dosage form for the delivery of a drug at a rate having a percentage deviation of not more than 5% from a mean release rate over a prolonged period of time, wherein the dosage form comprises:

(a) a drug composition;

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composition;

- (c) a hydrophilic polymer comprising a controlled particle size in the drug composition;
- (d) a means for delaying release of drug from the drug composition.

45. The dosage form of Claim 44 wherein the drug is verapamil hydrochloride.

46. The dosage form of Claim 44 wherein the drug possesses a controlled particle size of up to 150 μm and the hydrophilic polymer possesses a controlled particle size of up to 250 μm .

47. A method for the manufacture of a dosage form adapted to release a drug at a rate having a percentage deviation of not more than 5% from a mean release rate over a prolonged period of time comprising:

- (a) controlling a drug particle size;
- (b) controlling a hydrophilic polymer particle size;
- (c) admixing the drug with the hydrophilic polymer;
- (d) providing a means for prolonging release of the drug.

48. A method for the manufacture of a dosage form according to claim 47 wherein the drug is verapamil hydrochloride.

49. A method for the manufacture of a dosage form according to claim 47 wherein the prolonged release is four hours or more.

50. A method for the manufacture of a dosage form according to claim 47 wherein the drug particle size is controlled to up to 150 μm , and the hydrophilic polymer particle size is controlled to up to 250 μm .

51. A method for maintaining a percentage deviation in a drug release rate of not more than 5% from the mean release rate over a prolonged period of time comprising:

- (a) controlling a drug particle size;
- (b) controlling a hydrophilic polymer particle size;
- (c) admixing the drug with the hydrophilic polymer;
- (d) providing a means for prolonging release of the drug.

52. A method for providing a controlled drug rate of release from a dosage form in a patient, wherein the method comprises:

- (a) admitting orally into the patient a therapeutic composition comprising a dose of drug with the drug possessing a controlled particle size, and a hydrophilic polymer for the drug possessing a controlled particle size; and

- (b) codelivering the drug and the accompanying hydrophilic polymer at a substantially constant rate of release from the composition to provide an effective therapeutic dose in the patient.

53. The method for providing a controlled drug rate of release from a dosage form in a patient according to claim 52, wherein the substantially constant rate of release from the composition has a percentage deviation of not more than 5% from the mean release rate over a prolonged period of time.

54. The method for providing a controlled drug rate of release from a dosage form in a patient according to claim 53, wherein the prolonged period of time is four hours or more.

55. The method for providing a controlled drug rate of release from a dosage form in a patient according to claim 52, wherein the controlled particle size of the drug is up to 150 μm , and the controlled particle size of the hydrophilic polymer is up to 250 μm .

56. A method for providing a rate of release from a dosage form in a patient having a percentage deviation of not more than 5% from the mean release rate over a prolonged period of time, wherein the method comprises:

- (a) admitting orally into the patient a therapeutic composition comprising a

- (a) admitting orally into the patient a therapeutic composition comprising a dose of drug with the drug possessing a controlled particle size, and a hydrophilic polymer possessing a controlled particle size; and
- (b) codelivering the drug and the accompanying hydrophilic polymer at a substantially constant rate of release from the composition to provide an effective therapeutic dose in the patient.

57. The method for providing a controlled drug rate of release from a dosage form in a patient according to claim 56, wherein the prolonged period of time is four hours or more.

58. The method for providing a controlled drug rate of release from a dosage form in a patient according to claim 56, wherein the drug possesses a controlled particle size of up to 150 μm , and the hydrophilic polymer possesses a controlled particle size of up to 250 μm .

REMARKS

Claims 1-43 are cancelled without prejudice.

Claims 44-58 were added.

Attached hereto is a clean copy of the changes made to the claims by the current amendment. The attached page is captioned "Clean Copy of Claims."

CONCLUSION

Applicants respectfully submit that the claims are novel and nonobvious. Accordingly, allowance is believed to be in order and an early notification to that effect would be appreciated.

Respectfully submitted,

Date: September 25, 2001

By: _____

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CLEAN COPY OF CLAIMS

In the claims:

Claims 1-43 have been canceled.

Claims 44-58 have been added as follows:

44. A dosage form for the delivery of a drug at a rate having a percentage deviation of not more than 5% from a mean release rate over a prolonged period of time, wherein the dosage form comprises:

- (e) a drug composition;
- (f) a dose of drug comprising a controlled particle size in the drug composition;
- (g) a hydrophilic polymer comprising a controlled particle size in the drug composition;
- (h) a means for delaying release of drug from the drug composition.

45. The dosage form of Claim 44 wherein the drug is verapamil hydrochloride.

46. The dosage form of Claim 44 wherein the drug possesses a controlled particle size of up to 150 μm and the hydrophilic polymer possesses a controlled particle size of up to 250 μm .

47. A method for the manufacture of a dosage form adapted to release a drug at a rate having a percentage deviation of not more than 5% from a mean

release rate over a prolonged period of time comprising:

- (e) controlling a drug particle size;
- (f) controlling a hydrophilic polymer particle size;
- (g) admixing the drug with the hydrophilic polymer;
- (h) providing a means for prolonging release of the drug.

48. A method for the manufacture of a dosage form according to claim 47 wherein the drug is verapamil hydrochloride.

49. A method for the manufacture of a dosage form according to claim 47 wherein the prolonged release is four hours or more.

50. A method for the manufacture of a dosage form according to claim 47 wherein the drug particle size is controlled to up to 150 μm , and the hydrophilic polymer particle size is controlled to up to 250 μm .

51. A method for maintaining a percentage deviation in a drug release rate of not more than 5% from the mean release rate over a prolonged period of time comprising:

- (e) controlling a drug particle size;
- (f) controlling a hydrophilic polymer particle size;
- (g) admixing the drug with the hydrophilic polymer;

- (h) providing a means for prolonging release of the drug.

52. A method for providing a controlled drug rate of release from a dosage form in a patient, wherein the method comprises:

- (c) admitting orally into the patient a therapeutic composition comprising a dose of drug with the drug possessing a controlled particle size, and a hydrophilic polymer for the drug possessing a controlled particle size; and

- (d) codelivering the drug and the accompanying hydrophilic polymer at a substantially constant rate of release from the composition to provide an effective therapeutic dose in the patient.

53. The method for providing a controlled drug rate of release from a dosage form in a patient according to claim 52, wherein the substantially constant rate of release from the composition has a percentage deviation of not more than 5% from the mean release rate over a prolonged period of time.

54. The method for providing a controlled drug rate of release from a dosage form in a patient according to claim 53, wherein the prolonged period of time is four hours or more.

55. The method for providing a controlled drug rate of release from a dosage

form in a patient according to claim 52, wherein the controlled particle size of the drug is up to 150 μm , and the controlled particle size of the hydrophilic polymer is up to 250 μm .

56. A method for providing a rate of release from a dosage form in a patient having a percentage deviation of not more than 5% from the mean release rate over a prolonged period of time, wherein the method comprises:

(c) admitting orally into the patient a therapeutic composition comprising a dose of drug with the drug possessing a controlled particle size, and a hydrophilic polymer possessing a controlled particle size; and

(d) codelivering the drug and the accompanying hydrophilic polymer at a substantially constant rate of release from the composition to provide an effective therapeutic dose in the patient.

57. The method for providing a controlled drug rate of release from a dosage form in a patient according to claim 56, wherein the prolonged period of time is four hours or more.

58. The method for providing a controlled drug rate of release from a dosage form in a patient according to claim 56, wherein the drug possesses a controlled particle size of up to 150 μm , and the hydrophilic polymer possesses a controlled particle size of up to 250 μm .